K132696

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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	September 27, 2013
Owner/Submitter:	GE Healthcare Finland Oy Kuortaneenkatu 2 FIN-00510 Helsinki, Finland
Primary Contact Person:	Joel Kent Manager, Quality and Regulatory Affairs GE Healthcare Phone: 781-449-8685 Fax: 781-433-1344 E-mail: joel.kent@ge.com
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Device names (807.92(a)(2)):	Device Trade Name: TruSignal® SpO2 Adult and Pediatric Adhesive Wrap Disposable Sensors Common/Usual Name: Pulse Oximeter Sensors Classification Names: 21 CFR 870.2700 Oximeter
Product Code:	DQA

SEP 27 2013

Predicate Device(s) (807.92(a)(3):	TruSignal SpO2 Allfit Sensor cleared in K093881 TruSignal® Sensors and Interconnect Cables
Device Description (807.92(a)(4)):	The TruSignal SpO2 Adult and Pediatric Disposable Sensors are used together with standalone oximeters or modular patient monitors to measure continuous non-invasive arterial oxygen saturation (SpO2) and pulse rate monitoring. The sensors are to be connected to a device using an interconnect cable TS-G3, TS-M3, TS-H3 or TS-N3 (cleared in K093881). The interconnect cable type depends on the monitor end connector of the device. The sensors contain light emitting diodes (LEDs) that emit light of different wavelengths. The sensors also contain a photodetector for detecting the emitted light after it has been attenuated by tissue. The sensors further contain a resistor, which is used to encode the wavelength of the LEDs used in the sensor. The resistor value is read by the monitor to determine the calibration curve used for that specific sensor.
Intended Use (807.92(a)(5):	<u>TS-AAW-10 and TS-AAW-25</u> The Disposable Sensor is a single-patient use sensor intended for continuous non-invasive arterial oxygen saturation (SpO2) and pulse rate monitoring. Patient weight range: > 20 kg (>44 pounds) <u>TS-PAW-10 and TS-PAW-25</u> The Disposable Sensor is a single-patient use sensor intended for continuous non-invasive arterial oxygen saturation (SpO2) and pulse rate monitoring. Patient weight range: 3-20 kg (6.6-44 pounds)
Technology (807.92(a)(6)):	The TruSignal SpO2 Adult and Pediatric Disposable Sensors employ the same fundamental scientific technology as their predicate device TruSignal SpO2 Allfit Sensor K093881. The following is an overview of the differences between the proposed TruSignal SpO2 Adult and Pediatric Disposable Sensors and the predicate device: • Patient Population Equivalent to the predicate device: o Patient weight range has been changed from all patients of the predicate device to 3-20 kg (6.6-44 pounds) of the TS-PAW proposed device and > 20 kg (>44 pounds) of the TS-AAW proposed device. o Applicable Electromagnetic Compatibility, Electrical safety, Usability, biocompatibility, engineering verification tests (such as cleaning, and material durability) and clinical performance testing test report show that the proposed device is as safe and effective as the predicate K093881.

	• Anatomical Sites Equivalent to the predicate device: o Palm of the hand and side of the foot excluded from the application sites. o Applicable Electromagnetic Compatibility, Electrical safety, Usability, biocompatibility, engineering verification tests (such as cleaning, and material durability) and clinical performance testing test report show that the proposed device is as safe and effective as the predicate K093881 • Environment of Use Equivalent to the predicate device: o Step down units added to the list of environments of use of the proposed device. ESU removed from the list of environments of use of the proposed device. o Applicable Electromagnetic Compatibility, Electrical safety, Usability, biocompatibility, engineering verification tests (such as cleaning, and material durability) and clinical performance testing test report show that the proposed device is as safe and effective as the predicate K093881. • Sensor head o Geometry and dimensions o TS-AAW-10 and TS-AAW-25: Identical to the predicate device. o TS-PAW-10, TS-PAW-25: Equivalent to the predicate device: Geometry is identical to the predicate device. The distance of the optical components have been changed to be slightly less compared to the predicate device to better fit the finger of the smaller pediatric patients. o Applicable Electromagnetic Compatibility, Electrical safety, Usability, biocompatibility, engineering verification tests (such as cleaning, and material durability) and clinical performance testing test report show that the proposed device is as safe and effective as the predicate K093881. • Materials Equivalent to the predicate device in terms of intended use. o Applicable Electromagnetic Compatibility, Electrical safety, Usability, biocompatibility, engineering verification tests (such as cleaning, and material durability) and clinical performance testing test report

	show that the proposed device is as safe and effective as the predicate K093881. • Electro-optical components Equivalent to the predicate device: o Identical LEDs, detector and leadframes. The color of the sensor head have been changed from light pink of the predicate device to white of the proposed device. o Applicable Electromagnetic Compatibility, Electrical safety, Usability, biocompatibility, engineering verification tests (such as cleaning, and material durability) and clinical performance testing test report show that the proposed device is as safe and effective as the predicate K093881. • Performance Equivalent to the predicate device: o Accuracy of the TruTrak®, TruTrak+® technologies changed to A_rms ± 2.5 digits in the range of 70% to 100% SpO2 compared to ± 2 digits in the range of 70% to 100% SpO2 of the predicate device. o Accuracy of the Datex Ohmeda technology changed to A_rms ± 2.5 digits in the range of 70% to 100% SpO2 compared to ± 3 digits in the range of 70% to 100% SpO2 of the predicate device. o Applicable Electromagnetic Compatibility, Electrical safety, Usability, biocompatibility, engineering verification tests (such as cleaning, and material durability) and clinical performance testing test report show that the proposed device is as safe and effective as the predicate K093881 • Biocompatibility: Identical to the predicate device. o No change in the Body Contact materials • Connector Geometry and dimensions Equivalent to the predicate device: o The mating part of the connector is identical to the predicate device. The size of the connector body of the proposed devices is made smaller to reduce the amount of material needed. o Applicable Electromagnetic Compatibility, Electrical safety, Usability, biocompatibility, engineering verification tests (such as cleaning, and material durability) and clinical performance testing test report

	show that the proposed device is as safe and effective as the predicate K093881. • Materials (non body contact) Equivalent to the predicate device: o Connector body materials have been changed compared to the predicate device. Conductor insulation and outer jacket materials have been changed compared to the predicate device. Raw cable tissue paper was removed from the raw cable of the proposed device. o Applicable Electromagnetic Compatibility, Electrical safety, Usability, biocompatibility, engineering verification tests (such as cleaning, and material durability) and clinical performance testing test report show that the proposed device is as safe and effective as the predicate K093881. • Cable lengths Equivalent to the predicate device: o Applicable Electromagnetic Compatibility, Electrical safety, Usability, biocompatibility, engineering verification tests (such as cleaning, and material durability) and clinical performance testing test report show that the proposed device is as safe and effective as the predicate K093881. • Compatibility with other devices Equivalent to the predicate device: o Removed discontinued platforms from the compatibility list of the proposed devices and added platforms released after the clearance of the predicate device. o Applicable Electromagnetic Compatibility, Electrical safety, Usability, biocompatibility, engineering verification tests (such as cleaning, and material durability) and clinical performance testing test report show that the proposed device is as safe and effective as the predicate K093881. • Electrical Safety Identical to the predicate device K093881. • Thermal Safety Identical to the predicate device K093881. This comparison of the specifications demonstrates the functional equivalence of the products. The differences discussed do not raise new issues of safety and effectiveness. Verification and Validation testing demonstrated that no adverse effects have been introduced by these differences. GE Healthcare believes that the TruSignal SpO2 Adult and Pediatric

	Disposable Sensors are as safe and effective, and perform in a substantially equivalent manner to the predicate TruSignal® SpO2 Allfit sensor (K093881).
Determination of Substantial Equivalence (807.92(b)(1)):	Summary of Non-Clinical Tests: The TruSignal SpO2 Adult and Pediatric Disposable Sensors and its applications comply with voluntary standards. The following quality assurance measures were applied to the development of the system: Risk Analysis Requirements Reviews Design Reviews Testing on unit level (Module verification) Integration testing (System verification) Performance testing (Verification) Safety testing (Verification) Simulated use testing (Validation) The TruSignal SpO2 Adult and Pediatric Disposable was designed and tested for compliance to the following standards: 1. IEC 60601-1 2005; Medical Electrical Equipment – Part 1: General Requirements for Safety 2. IEC 60601-1-2; Ed3. 2007; Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests 3. ISO 9919 2009; Medical electrical equipment – Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use 4. ISO 10993-1:2009; Biological evaluation of medical devices 5. IEC 60601-1-6:2010 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability – Edition 3.0 6. IEC 62366:2007 Medical devices – Application of usability engineering to medical devices – Edition 1.0
Clinical (807.92(b)(2)):	Summary of Clinical Tests: Clinical verification tests were performed on the proposed devices on an extensive selection of GE patient monitors. TruSignal SpO2 Adult Disposable Sensor: The test consisted of induced hypoxia studies on healthy adult volunteers (ages 19-31 yr. with light to dark pigmentation) during non-motion conditions

	conducted in an independent research laboratory. The measured arterial hemoglobin saturation values of the proposed devices were compared to CO-oximeter based arterial hemoglobin saturation values. The proposed sensor was shown to have an A_RMS of less than 2 during steady state conditions over the range of 70-100%. The S5 Compact Monitors with an E-PRESTN module meets an A_RMS of less than 2.5% for the same range. The results of the study provide supporting evidence that the SpO2 accuracy performance of the new design of the GE Healthcare disposable sensors does not adversely affect the SpO2 accuracy performance and the proposed sensors pass the respective A_RMS specifications under steady state / non-motion conditions for the range 70-100% as stated in the Instructions for use. TruSignal SpO2 Pediatric Disposable Sensor did not require clinical studies to support substantial equivalence. TruSignal SpO2 Pediatric Disposable Sensor has identical materials and electro-optical components and equivalent sensor characteristics to TruSignal SpO2 Adult Disposable Sensor, thus the clinical data from Adult Disposable Sensor applies to this sensor as well.
Conclusion (807.92(b)(3)):	GE Healthcare considers the TruSignal SpO2 Adult and Pediatric Disposable Sensors to be as safe, as effective, and performance is substantially equivalent to the predicate device TruSignal SpO2 Allfit Sensor (K093881).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 27, 2013

GE Healthcare
Mr. Joel Kent
Manager, Quality and Regulatory Affairs
Kuortaneenkatu 2
FIN-00510 Helsinki, Finland

Re: K132696
Trade/Device Name: TruSignal SpO2 Adult and Pediatric Disposable Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: August 28, 2013
Received: August 29, 2013

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

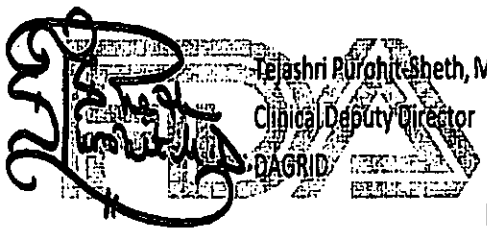
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K132696

Device Name: TruSignal® SpO2 Adult and Pediatric Disposable Sensors

Indications for Use:

TS-AAW-10 and TS-AAW-25

The Disposable Sensor is a single-patient use sensor intended for continuous non-invasive arterial oxygen saturation (SpO2) and pulse rate monitoring. Patient weight range: > 20 kg (>44 pounds)

TS-PAW-10 and TS-PAW-25

The Disposable Sensor is a single-patient use sensor intended for continuous non-invasive arterial oxygen saturation (SpO2) and pulse rate monitoring. Patient weight range: 3-20 kg (6.6-44 pounds)

Prescription Use X (Part 21 CFR 801 Sub part D) AND/OR Over-The-Counter Use ____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nayan J. Patel -S
2013.09.26 17:47:51 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K132696